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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/679,664	10/03/2000	Thomas M. Stormann	072827-1801	7662

7590 04/29/2004  
Richard J. Warburg  
FOLEY & LARDNER  
23rd Floor  
402 West Broadway  
San Diego, CA 92101-3542

EXAMINER
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LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 04/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/679,664

**Applicant(s)**

STORMAN ET AL.

**Examiner**

Robert Landsman

**Art Unit**

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 42-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 42-62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 09, 2004 has been entered.

#### ***1. Formal Matters***

- A. Claims 1-11 and 42-62 are pending and are the subject of this Office Action.
- B. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

#### ***2. Claim Rejections - 35 USC § 112, first paragraph - scope of enablement***

- A. Claims 1-11 and 42-62 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 2-3 of the Office Action dated 2/26/03 and which are restated on the Advisory Action dated 12/31/03. Applicants argue that, in accordance with the discussion in the Telephonic Interview on January 21, 2004, Applicant has amended claim 1 to specify that the G-protein receptor domain sequences have at least 75% sequence identity with the respective mGluR, CaR, or GABA-B domain sequences. Applicants argue that one of ordinary skill in the art will recognize that functional receptors with this level of sequence identity to wild-type domain sequences can readily be designed and constructed.

Applicants further state that they will submit a Declaration confirming that functional receptors can be constructed that have a short intracellular domain sequence, i.e., at least 10 amino acid residues in length as specified in claim 1. Applicant appreciates the Examiner's indication that he would consider such a Declaration. In view of the fact that functional receptors with modified domain sequences and with intracellular domain sequences that may be shortened can be constructed, Applicant respectfully submits that the claims are fully enabled, and requests that the Examiner reconsider and withdraw these rejections.

These arguments have been considered, but, respectfully, are not deemed persuasive. The Examiner does recall the Telephone Interview of January 21, 2004 wherein percent identity was

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discussed. Applicants did state in that interview that the invention was the actual fusion of the intracellular domain to the However, as previously argued, altering 10-25% of these receptor regions would mean altering from 20 (out of 200 residues) up to potentially 150 (out of 600 residues). Not only is there no guidance or working examples of altering up to 25% of the domains, but Applicants have not taught that altering 25% of domains *from three distinct receptors* could still produce a functional receptor. Applicants argue that these types of receptors can readily be designed and constructed. However, the specification does not teach the artisan which residues can be altered while retaining the functional characteristics of the receptor regions, *especially in light of the fact that the claims do not provide any functional limitation, including the requirement to bind a particular ligand*. Without this guidance it is not predictable to the artisan how to alter residues in these regions while maintaining the functional characteristics of these regions, or, more importantly, the receptor has a whole. This receptor is a chimera of potentially 3 distinct receptors. Applicants have only shown chimeras between two receptors, both of *full-length*. In addition, Applicants have only used one G protein,  $G\alpha_{i5}$ . The specification does not disclose what other G proteins can be used to functionally couple the chimeric receptor to intracellular signal transduction pathways. Furthermore, the claims remain rejected since, at the time of this Office Action, Applicants have not submitted a Declaration discussing the limitation that the intracellular loop can be as few as 10 amino acids and still be functional. Again, this loop is hundreds of amino acids in length. The specification does not teach that intracellular domains as few as 10 amino acids in length can bind, not only one G protein, but various G proteins which are able to couple the receptor to intracellular pathways.

### **3. Claim Rejections - 35 USC § 103**

A. The rejection of claims 1-11 and 42-62 under 35 USC 103 has been withdrawn in view of Applicants' arguments that Bertin et al., the primary reference, describes fusion of a specific type of receptor, an adrenoreceptor, to G-protein alpha subunit with which the adrenoreceptor normally associates, in order to isolate the G-protein interaction to the single G-protein as a method of analyzing the pathways activated by the receptor through that G-protein. Nothing in this reference suggests signal transduction switching or any other use of a non-natural G-protein as specified in present claim 1.

### **4. Conclusion**

A. No claim is allowable.

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***Advisory information***

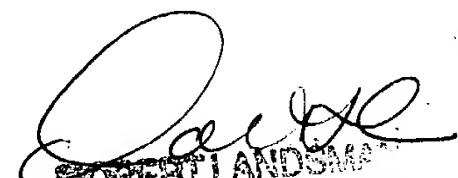
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.  
Patent Examiner  
Group 1600  
April 27, 2004



ROBERT LANDSMAN  
PATENT EXAMINER